



## Talon Therapeutics, Inc. Reports Fourth Quarter and Year End 2011 Financial Results

SAN MATEO, Calif., March 29, 2012 (GLOBE NEWSWIRE) -- Talon Therapeutics, Inc., (OTCBB:TLON), today reported financial results for the fourth quarter and year ended December 31, 2011, and provided a corporate update.

"Our primary corporate focus for the past year has been the development of Marqibo with the objective of receiving FDA approval," stated Steven R. Deitcher M.D., President, Chief Executive Officer and Board Member of Talon Therapeutics. "A key step in the FDA approval process is the Oncologic Drugs Advisory Committee (ODAC) meeting, which was held on March 21, 2012. We were very pleased with the positive vote by ODAC supporting Marqibo's benefit/risk assessment for our sought indication. We look forward to working with the FDA over the coming weeks leading up to the May 13, 2012 PDUFA date," Dr. Deitcher added.

### 2011 Corporate Highlights

- Submission of NDA for Marqibo seeking accelerated approval in adult Philadelphia negative (Ph-) acute lymphoblastic leukemia (ALL) in second or greater relapse or that has progressed following two or more lines of anti-leukemia therapy. The NDA was accepted for filing under subpart H- Accelerated Approval in September 2011.
- Agreement reached with the FDA in August 2011 for a Special Protocol Assessment (SPA) for the Company's Phase 3 confirmatory study for Marqibo in front-line-elderly ALL.
- Initiation and enrollment of multiple patients in a Phase 3 study of Marqibo in elderly patients with newly diagnosed aggressive Non-Hodgkin's Lymphoma being conducted by the German High-Grade Non-Hodgkin's Lymphoma Study Group.
- Enrollment of first patient in a Phase 1 trial of Marqibo in children and adolescents with relapsed or refractory cancer being conducted by the Pediatric Branch of the National Cancer Institute.
- Meeting with the European Medicines Agency (EMA) seeking Scientific Advice for a Marketing Authorization Application for Marqibo in Europe.
- Enrollment of the first patient in a Phase 2 study of Menadione Topical Lotion conducted and sponsored by Mayo Clinic.

### Three Months Ended December 31, 2011 Unaudited Financial Results

For the three months ended December 31, 2011, the Company reported a net loss of \$1.7 million and deemed dividends on preferred stock of \$1.0 million, which when combined, resulted in a net loss applicable to common stockholders of \$2.7 million, or \$0.12 per share. The deemed dividends on preferred stock attributed \$0.05 per share to the total net loss applicable to common stockholders for the three months ended December 31, 2011. This compares with a net loss of \$6.3 million and deemed dividends on preferred stock of \$0.9 million, which when combined, resulted in a net loss applicable to common stockholders of \$7.2 million, or \$0.34 per share, for the three months ended December 31, 2010.

Total operating expenses for the three months ended December 31, 2011, were \$3.7 million, compared with \$6.5 million for the three months ended December 31, 2010. Research and development expenses were \$2.3 million for the three months ended December 31, 2011, compared with \$5.2 million for the three months ended December 31, 2010. General and administrative expenses were \$1.4 million for the three months ended December 31, 2011, compared with \$1.3 million for the three months ended December 31, 2010.

Cash used in operations was \$3.6 million for the three months ended December 31, 2011. As of December 31, 2011, the Company had cash and cash equivalents of \$1.0 million. Following the end of the 2011 fiscal year, on January 9, 2012, the Company completed an \$11 million preferred stock financing.

### Year Ended December 31, 2011 Financial Results

For the year ended December 31, 2011, the Company reported a net loss of \$18.8 million and deemed dividends on preferred stock of \$3.9 million, which when combined, resulted in a net loss applicable to common stockholders of \$22.7 million, or \$1.06 per share. The deemed dividends on preferred stock attributed \$0.18 per share to the total net loss applicable to common stockholders for the year ended December 31, 2011. This compares with a net loss of \$26.0 million and deemed dividends on preferred stock of \$32.3 million, which when combined, resulted in a net loss applicable to common stockholders of \$58.3 million, or \$2.81 per share, for the year ended December 31, 2010.

Total operating expenses for the year ended December 31, 2011, were \$18.5 million, compared with \$25.8 million for the year

ended December 31, 2010. Research and development expenses were \$13.4 million for the twelve months ended December 31, 2011, compared with \$20.2 million for the year ended December 31, 2010. General and administrative expenses were \$5.1 million for the year ended December 31, 2011, compared with \$5.6 million for the year ended December 31, 2010.

Cash used in operations was \$21.9 million for the year ended December 31, 2011.

### **About Marqibo(R) (vincristine sulfate liposome injection)**

Marqibo is a novel, targeted Optisome™ encapsulated formulation product candidate of the FDA-approved anticancer drug vincristine. Talon is primarily developing Marqibo for the treatment of Ph- adult ALL. Vincristine, a microtubule inhibitor, is FDA-approved for ALL and is widely used as a single agent and in combination regimens for treatment for hematologic malignancies such as lymphomas and leukemias. Talon's encapsulation formulation is designed to provide prolonged circulation of the drug in the blood and accumulation at the tumor site. These characteristics are intended to increase the dose of vincristine delivered in a safe and effective manner.

Talon has received orphan drug and fast track designations for Marqibo for the treatment of adult ALL from the U.S. Food and Drug Administration. Marqibo has also received orphan drug designation in adult ALL from the European Medicines Evaluation Agency.

### **About Talon Therapeutics**

Talon Therapeutics, Inc. is a biopharmaceutical company dedicated to seizing upon medical opportunities, efficiently and expertly leading product candidates through clinical development, and transferring value to patients, patient care providers, shareholders, corporate partners, and employees.

In addition to Marqibo and Menadione Topical Lotion, the Company has additional pipeline opportunities some of which, like Marqibo, improve delivery and enhance the therapeutic benefits of well characterized, proven chemotherapies and enable high potency dosing without increased toxicity.

Additional information on Talon Therapeutics can be found at [www.talontx.com](http://www.talontx.com).

The Talon Therapeutics, Inc. logo is available at <http://www.globenewswire.com/newsroom/prs/?pkgid=3290>

### **Forward-Looking Statement**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements are often, but not always, made through the use of words or phrases such as "anticipates," "expects," "plans," "believes," "intends," and similar words or phrases. These forward-looking statements include without limitation, statements regarding Talon's ability to obtain accelerated approval of Marqibo for the treatment of adult Ph- ALL and the potential of Marqibo to replace existing therapies. Such statements involve risks and uncertainties that could cause Talon's actual results to differ materially from the anticipated results and expectations expressed in these forward-looking statements. These statements are based on current expectations, forecasts and assumptions that are subject to risks and uncertainties, which could cause actual outcomes and results to differ materially from these statements. Among other things, there can be no assurances that any of Talon's clinical and regulatory development efforts relating to Marqibo will be successful; that Talon's NDA for Marqibo will be approved; that the data of the clinical trials of Marqibo will be sufficient to support approval by the FDA of an NDA for Marqibo; that the results of the clinical trials of Marqibo support Talon's claims or beliefs concerning Marqibo's safety and effectiveness; that Talon will be able to secure the additional capital necessary to fund its product development programs, including Marqibo, to completion; and that the ODAC vote on Marqibo will be followed by the FDA. Other risks include Talon's reliance on third-party researchers to develop its product candidates, and its lack of experience in developing and commercializing pharmaceutical products. Additional risks are described in the company's Annual Report on Form 10-K for the year ended December 31, 2011. Talon assumes no obligation to update these statements, except as required by law.

## **TALON THERAPEUTICS, INC.**

### **BALANCE SHEETS**

	<b>December 31,</b>	<b>December 31,</b>
	<b>2011</b>	<b>2010</b>

#### **ASSETS**

Current assets:

Cash and cash equivalents	\$ 1,028,518	\$ 4,573,254
Available-for-sale, equity securities	—	74,000
Available-for-sale, debt securities	—	17,993,745
Prepaid expenses and other current assets	635,297	253,901
Total current assets	1,663,815	22,894,900
Property and equipment, net	72,431	97,231
Restricted cash	—	125,000
Debt issuance costs	751,401	904,909
Total assets	<u>\$ 2,487,647</u>	<u>\$ 24,022,040</u>

#### LIABILITIES AND STOCKHOLDERS' DEFICIT

##### Current liabilities:

Accounts payable and accrued liabilities	\$ 4,556,951	\$ 6,051,982
Other short-term liabilities	2,110	1,787

Total current liabilities	<u>4,559,061</u>	<u>6,053,769</u>
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Notes payable, net of discount	24,033,257	23,340,144
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Other long-term liabilities	2,474	4,753
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Investors' right to purchase future shares of Series A-1 and A-2 preferred stock	1,772,100	5,131,000
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Warrant liabilities, non-current	501,664	712,965
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Total long term liabilities	<u>26,309,495</u>	<u>29,188,862</u>
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Total liabilities	<u>30,868,556</u>	<u>35,242,631</u>
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##### Commitments and contingencies:

##### Redeemable convertible preferred stock; \$0.001 par value:

10 million shares authorized, 0.4 million shares issued and outstanding at December 31, 2011, and 2010; aggregate liquidation value of \$46.4 million and \$42.4 million at December 31, 2011 and December 31, 2010, respectively	30,643,219	30,643,219
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##### Stockholders' deficit:

##### Common stock; \$0.001 par value:

350 million shares authorized, 21.8 million and 21.2 million shares issued and outstanding at December 31, 2011 and December 31, 2010, respectively	21,779	21,234
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Additional paid-in capital	120,887,432	119,241,956
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Accumulated other comprehensive loss	—	(15,841)
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Accumulated deficit	(179,933,339)	(161,111,159)
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Total stockholders' deficit	<u>(59,024,128)</u>	<u>(41,863,810)</u>
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Total liabilities, redeemable convertible preferred stock and stockholders' deficit	<u>\$ 2,487,647</u>	<u>\$ 24,022,040</u>
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### TALON THERAPEUTICS, INC.

#### STATEMENTS OF OPERATIONS

	Three Months Ended December 31,		Years Ended December 31,	
	2011	2010	2011	2010
	(unaudited)	(unaudited)		
Operating expenses:				
General and administrative	\$ 1,398,422	\$ 1,270,891	\$ 5,121,678	\$ 5,570,820
Research and development	2,325,690	5,228,110	13,387,168	20,194,878

Total operating expenses	<u>3,724,112</u>	<u>6,499,001</u>	<u>18,508,846</u>	<u>25,765,698</u>
Loss from operations	(3,724,112)	(6,499,001)	(18,508,846)	(25,765,698)
Other income (expense):				
Interest income	158	11,227	8,124	49,247
Interest expense	(900,112)	(869,102)	(3,560,444)	(3,750,471)
Other expense, net	(2,768)	—	(78,768)	(3,512)
Change in fair value of warrant liabilities	454,187	(20,690)	(41,146)	(55,509)
Change in fair value of investors' right to purchase future shares of Series A-1 and A-2 preferred stock	<u>2,522,900</u>	<u>1,108,000</u>	<u>3,358,900</u>	<u>3,539,000</u>
Total other income (expense)	<u>2,074,365</u>	<u>229,434</u>	<u>(313,334)</u>	<u>(221,245)</u>
Net loss	\$ (1,649,747)	\$ (6,269,567)	\$ (18,822,180)	\$ (25,986,943)
Deemed dividends attributable to preferred stock	<u>(1,028,307)</u>	<u>(941,814)</u>	<u>(3,947,713)</u>	<u>(32,308,787)</u>
Net loss applicable to common stockholders	<u>(2,678,054)</u>	<u>(7,211,382)</u>	<u>(22,769,893)</u>	<u>(58,295,730)</u>
Net loss per share, basic and diluted	\$ (0.12)	\$ (0.34)	\$ (1.06)	\$ (2.81)
Weighted average shares used in computing net loss per share, basic and diluted	21,778,812	21,234,307	21,557,062	20,737,470

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